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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,611	11/21/2001	Lorraine Faxon Meisner	121753-1005	4194

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,611	MEISNER, LORRAINE FAXON	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-18 and 20-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-18 and 20-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-8,10-18,20-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant does not cite to anywhere in the Specification which provides support for the limitation "does not have any chemical stabilizers." The claims specifically claim such compounds such as cystine, cysteine, glutathione, methionine, propylene glycol, hydroxypropylcellulose, glycerol and sorbitol which are disclosed in the art to be stabilizers of ascorbic acid (See Opplt (US Pat. 2,585,580), Column 2, lines 34-50; Darr et al. (US Pat. 5,140,043), see entire reference; Wilmott et al. (US Pat. 4,983,382), Column 4, lines 14-68).

Claims 1, 3-8,10-18,20-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention:

The invention is directed to a composition comprising at least about 5.0% pre-treated ascorbic acid and water, having a pH of 3.5 to 4.1 and not containing any chemical stabilizers

The state of the prior art and the predictability or lack thereof in the art:

The prior art discloses amounts of ascorbic acid and pHs falling within the claimed invention by adding bases, such as sodium hydroxide and ammonium hydroxide. The prior art also discloses the use of stabilizers, such as cysteine, glutathione, methionine, propylene glycol, hydroxypropylcellulose, glycerol and sorbitol which are disclosed in the art to be stabilizers of ascorbic acid. See discussion above and below. Applicant however, argues, that "in the absence of treatments described in the present Application, a 5%(w/v) aqueous solution of ascorbic acid will not be stable a pH values greater than 3.5" and that use of bases, such as triethanol amine, sodium hydroxide and ammonium hydroxide to modulate the pH, will deprotonate the ascorbic acid. As such, predictability in the art appears to be low.

The amount of direction or guidance present and the presence or absence of working examples:

As indicated above Applicant discloses and claims carriers, such as such as cystine, cysteine, glutathione, methionine, propylene glycol, hydroxypropylcellulose, glycerol and sorbitol which are disclosed in the art to be stabilizers of ascorbic acid (See above discussion, Specification, Pg. 9, lines 21-33, claims 6,16,17). The Specification does not appear to disclose the limitation "chemical stabilizers" much less indicate what and what is not include within the scope of said limitation. Applicant also discloses that the pH is adjusted by adding an appropriate amount of base such as sodium hydroxide or ammonium hydroxide (Pg. 9, lines 6-10, Pg. 10, lines 20-24). The Specification does provides examples of stable formulations, however, it appears that the formulations tested only contained water and ascorbic acid with no indication as to the pH of the formulations (Specification, pg. 7, lines 17-31).

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they are open ended, do not indicate how the pH is arrived at, do not define what is and what is not within the scope of chemical stabilizers and do not indicate what the chemical is a stabilizer for. Since the specification does not appear to indicated how to adjust the pH of the composition other than by adding a base and does not indicate what would or would not be include in the scope of the limitation "chemical stabilizers", one of ordinary skill in the art would be required to do undue experimentation in order to arrive at the claimed pH without using a base, which Applicant asserts will cause the composition to not contain ascorbic acid, and determine what compound will or will not act as a chemical stabilizer, notwithstanding the fact Applicant's Specification discloses the use of carriers which are disclosed by the art to be stabilizers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Examiner withdraws the rejection of claims 1-3,10,15-18,24,25 under 35 U.S.C. 102(b) over Duffy et al. (US Pat. 5,516,793) solely for the reason that Duffy does not disclose the exclusion of chemical stabilizers, not withstanding the fact that Applicant does not appear to address how the amendments overcome the prior art. Examiner has considered the Affidavit of Edward Mickleson but deems it unpersuasive. In the first instance, the conclusions are based are theoretical findings as to what would be the effect of the ammonium hydroxide on the ascorbic acid. Secondly, Applicant's own Specification discloses that ammonium hydroxide is suitable

for use to adjust the pH to the claimed values (Specification, Pg. 9, lines 5-12). Third, the present claims do not indicate any time period and Applicant has made no showing that at the initial point of mixture that the prior art composition did not have 5% or 10% ascorbic acid. Finally, the affidavit fails to account for the effects of the other components in the prior art compositions on the ascorbic acid; for example, as indicated above, propylene glycol and hydroxyethyl cellulose are disclosed to be stabilizers for ascorbic acid.

The rejection of claims 1-26 under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. in view of Murad, Herstein and Taylor et al. is withdrawn solely for the reason that the prior art does not disclose the exclusion of stabilizers.

Examiner has duly considered Applicant's other arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues that none of the prior art suggests having a pH of more than 3.5. The independent claims do not recite a pH of more than 3.5 but a range of 3.5 to 4.1. In any case, the

prior art does teach a pH of 3.5-4.1. Herstein teaches that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule (Column 10, lines 6-17). Applicant argues that Murad teaches away from having a pH of more than 3.5 because Murad discloses oral administration, however, Applicant has provided no showing that pH is irrelevant to oral administration. Even in tablets and capsules, pH is a factor which must be accounted for; for example, see Schonmann et al. (US Pat. 4,894,978), Column 6, lines 48-55). Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971).

Applicant argues that the use of bases such as triethanol amine, sodium hydroxide and ammonium hydroxide in Herstein will serve to deprotonate the ascorbic acid, yielding the unstable ascorbate anion. However, as admitted by Applicant, Herstein discloses that greater than 82% of the ascorbic acid in its composition remains protonated. With respect to Applicant's description of Taylor, the portions cited refer to preferred embodiements, which, as indicated above do not constitute a teaching away from a broader disclosure or nonpreferred embodiements. Taylor does not exclude the use of solublized ascorbic acid and Applicant's claims do not explicitly set forth limitations which indicated the amount of water which is contained in the claimed compositions.

Contrary to Applicant's arguments, there is motivation to combine or modify the prior art as indicated in the prior Office Actions. Further, as indicated above, there is no requirement that all components of the claimed invention be present in each of the references and the combined teachings of the prior art, as set forth in the prior Office Actions, suggests compositions having at least about 5.0% ascorbic acid. Applicant has made no showing that Applicant's treatments are

the only way that a 5% aqueous solution of ascorbic acid will be stable at pH values greater than 3.5. In any case, the claims do not require stability of the ascorbic acid and permit amounts less than 5% by use of the term "about", and the prior art discloses compositions having greater than 5%. As such, even if there was instability, Applicant has made no showing that the instability would be sufficient to cause the amount of ascorbic acid to be less than "about" 5% when starting at the higher concentrations of ascorbic acid. Applicant does not appear to address how the limitation "pre-treatment" avoids the prior art.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC
July 9, 2004

S. MARK CLARDY
PATENT EXAMINER
GROUP 1200
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